



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/511,685

04/22/2005

Einar Moen

Q-84077

4835

23373 7590 12/22/2008
SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

EXAMINER

SINGH, SATYENDRA K

ART UNIT

PAPER NUMBER

1657

MAIL DATE

DELIVERY MODE

12/22/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/511,685	Applicant(s) MOEN ET AL.	
	Examiner SATYENDRA K. SINGH	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-14, 25-27, 30-33, 35 and 37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-14, 25-27, 30-33, 35 and 37 is/are rejected.
- 7) ☒ Claim(s) 30 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 October 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 3rd 2008 (along with amendments to the specification) has been entered.

Claims 15-24, 28-29, 34 and 36 have been canceled by applicants.

Claims 11-14, 25-27, 30-33, 35 and newly added claim 37 (applicant's originally elected invention of group II, as currently amended; directed to "a sterile microorganism growth substrate") are being examined on their merits, herein.

Specification

This specification is objected for the following reasons:

The title of the invention "**Product**" is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed (see MPEP 606.01[R-2]).

The following title is suggested:

"A microorganism growth substrate comprising a biomass derived from methanotrophic bacterium"

Claim Objections

1. Claim 30 (as currently presented) is objected to under 37 CFR 1.75(c), as being of improper dependent form for **failing to further limit** the subject matter of a previous claims 11

Art Unit: 1657

or 37. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 30 recites “wherein the sterilized nutrient composition is a dried autolysate of **a bacterial biomass**”, which does not further limit the subject matter of claims 11 or 37, as they recite the biomass generated from bacterial cells comprising four specific bacterial species (see for example, the recitation of claim 11, in particular). Applicants are requested to appropriately amend claim 30 in order to further limit the inventions of broader claims from which it depends.

Claim Rejections - 35 USC § 112 First paragraph

It is noted that the microorganisms required for the claimed invention are now deposited under Budapest Treaty conditions and that the deposit declaration provided with the last response pertain to the same deposit accession numbers. It is submitted that the strain designations "Bath", "DB3", "DB4" and "DB5" as recited in the original written disclosure (see instant specification, page 3, in particular) and as now provided demonstrate that the strains are the same. Therefore, the first paragraph **rejection is withdrawn**.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

Art Unit: 1657

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names **joint inventors**. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 11-14, 25-27, 30-33, 35, and 37 (as currently presented) are rejected under 35 U.S.C. 103(a) as being unpatentable over Bothe et al (*Appl. Microbiol. Biotechnol.*, 2002; IDS) taken with Norferm, DA (Product brochure, 1998; IDS) and Larsen & Joergensen (*Appl. Microbiol. Biotechnol.*, 1996; IDS), and in view of Atlas & Parks (Handbook of Microbiological Media, 1993 edition; [U]) and Patz et al (DD 290,917; IDS, an English translation was provided by the office in previous office action).

Claims are generally directed to a **sterile microorganism growth substrate** comprising: (a) a sterilized nutrient composition, wherein said composition is a sterile- biomass generated from bacterial cells by autolysis, followed by ultrafiltration and evaporation, wherein said bacterial cells comprise *Methylococcus capsulatus* (Bath) (strain NCIMB 41526), *Ralstonia* sp. DB3 (strain NCIMB 41527), *Aneurinibacillus* sp. DB4 (strain NCIMB 41528) and *Brevibacillus agri* DB5 (strain NCIMB 41525); (b) at least one sterile nutrient, which is a carbon source, added to the biomass, and (c) optionally a sterile diluent (see recitations of claims 11-14, 25-27, 30-33, 35, and newly added claim 37).

"[E]ven though **product-by-process claims** are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)

Bothe et al (IDS) disclose a composition (i.e. a bacterial biomass) comprising biomass generated from bacterial cells, wherein bacterial cells comprising at least one species of methanotrophic bacteria (such as *M. capsulatus* (Bath) NCIMB 11132) (see Bothe et al, abstract,

Art Unit: 1657

page 34, materials & methods, in particular; and the disclosure of the protein-rich biomass obtained from said bacterium grown on methane as a carbon source, oxygen, ammonia, and minerals, and water in a reactor, and centrifuged, **ultrafiltered**, heat-inactivated, and finally **spray-dried** (i.e. evaporated) in the form of a free-flowing, granulated product that is suitable for various applications as a high protein and nutrient source (see Norferm, DA, product brochure, 1998 for “BioProtein”) and at least one species of heterotrophic bacteria (such as *Ralstonia* sp., **DB3**; *Aneurinibacillus* sp., **DB4**; or *Brevibacillus* sp, **DB5**; see Bothe et al, abstract, pages 34, 35 and 38, in particular), at least one sterile nutrient (such as components of nitrate/mineral salts, NMS medium as described by Larsen & Joergensen; cited on page 138, left column, in particular).

However, a sterile microorganism growth substrate comprising a biomass generated by **autolysis**, and at least one sterile nutrient, which is a carbon source, comprising at least one **sterile nutrient** added to the biomass, such as **glucose**, or a combination of nitrate and mineral salts that is present in a **weight ratio on a dry mass basis** (as specifically recited in instant claims), is not explicitly disclosed by the combined disclosures of Bothe et al (taken with the disclosures of Norferm, DA and Larsen & Joergensen).

Atlas & Parks [U] provide the detailed disclosure about various nutrient media compositions (i.e. sterile microorganism growth substrates) routinely used for the cultivation of microorganisms (on solid as well as liquid media) including methanotrophic and heterotrophic bacteria (see Atlas & parks, for various methanotrophic bacteria, pages 574-579; and for heterotrophs such as various lactic acid bacteria and *Lactobacillus* species, pages 483-488, in particular). Atlas & Parks teach the use of **glucose as a sterile nutrient** for use in various media compositions routinely used for cultivation of various microbial species (see Atlas & Parks, pages 576, 483-488, in particular), and also the use of **nitrate and mineral salts** (see Atlas & Parks, pages 574-575, in addition to the teachings from Larsen & Joergensen, page 138, left

Art Unit: 1657

column, 1st paragraph, in particular) in the cultivation of microorganisms (being especially useful in the cultivation of methanotrophic bacteria). In addition, Atlas & Parks teach the fact that all growth media (be it solid or liquid) are customarily autoclaved (or filtered sterilized for heat sensitive biologic materials, such as vitamins, etc.) before use in the preparation of a microbial growth substrate to be useful in the processes of growing or culturing desired microorganisms (see sections on the “Preparation of Medium”, page 577, in particular).

Patz et al [U] teach a microorganism growth substrate comprising a nutrient composition (chemical thermal **hydrolysate**; see Patz et al, page 3, substance of the invention, and page 5, first paragraph, and example 1, in particular; taken as an autolysate of a methanotrophic bacteria) generated from the biomass of a culture of methanotrophic bacteria (a methylotrophic bacteria such as *Methylobacterium rhodesianum* IMET 11401; see Patz et al, page 1, claims and page 3, substance of the invention, in particular) further comprising at least one sterile nutrient (such as methanol as a carbon source, and optionally containing a diluent (such as water; see Patz et al, example 1 and 2, pages 6 and 7, in particular). Patz et al also teach sterile nutrient medium for fermentation of bacteria containing nitrate and mineral salts and combinations thereof (such as iron, copper, magnesium, manganese, zinc, nickel, boron, calcium, potassium, sodium, cobalt; see Patz et al, page 7, in particular). Thus, they demonstrate the fact that a hydrolysate (i.e. in the absence of any structural difference recited in the claims, taken as autolysate) derived from a methanotrophic bacterial biomass can be effectively used as a growth substrate for microorganisms such as bacteria.

Therefore, given the detailed disclosure for the components of the claimed microorganism growth substrate composition in the cited prior art references, it would have been

Art Unit: 1657

obvious to a person of ordinary skill in the microbiological art, at the time this invention was made, to modify the growth substrate composition (i.e. comprising the biomass) of Bothe et al (taken with the disclosures of Norferm, DA and Larsen & Joergensen, as discussed above) such that the growth substrate comprises an autolysed biomass generated from the methanotrophic and heterotrophic bacteria (as disclosed by Bothe et al), and a sterile nutrient as a carbon source, such as glucose, and further contains nitrate and mineral salts, and/or a combinations thereof, as explicitly suggested and disclosed by Atlas & parks (in view of Patz et al), and is sterilized using art-recognized means in order to be suitable for use as a sterile composition for growth of desired microorganisms.

The person of ordinary skill would be motivated to modify the growth substrate composition comprising the lysed biomass generated from methanotrophic and heterotrophic bacterial cultures (strains as specifically taught by Bothe et al taken with Patz et al) because the sterile nutrient compositions containing glucose, nitrate and mineral salts have been routinely used in the cultivation of various microorganisms (including methanotrophic as well as heterotrophic microorganisms) as explicitly disclosed by Atlas & parks (see discussion, supra). Furthermore, given the disclosure of Patz et al for the use of a lysed bacterial biomass (a methanotrophic **bacterial hydrolysate** used as a nutrient source; see disclosure above) for cultivation of bacteria, an artisan of ordinary skill in the microbial fermentation art would be highly motivated to use this protein-rich biomass generated from methanotrophic bacteria (that typically grow along with specific heterotrophic bacteria as discussed above), as a nutrient source when making a sterile growth substrate composition (for example, a culture medium) suitable for growth of various microorganisms.

Art Unit: 1657

One of ordinary skill in the microbial art would have had a reasonable expectation of success when modifying the composition according to the disclosures of Atlas & Parks and Patz et al, because the prior art references have explicitly disclosed the amounts, ratios and method of preparation (including method of sterilization, such as autoclaving and filter sterilization) of such sterile growth media/substrate compositions that are useful in cultivation of various microorganisms.

Although, the cited prior art references do not explicitly teach a microorganism growth substrate composition wherein the sterile nutrient such as glucose, or a combination of nitrate and mineral salts are present in specific **dry mass basis** (as recited in the instant claims) in relation to the sterile biomass (obtained from the culture of methanotrophic and heterotrophic bacteria) used in the invention as claimed, use of such specific ratios of required nutrients (alone as well as in combinations thereof) in relation to the biomass used in said composition would have been obvious and routine to a person of ordinary skill in the microbial art (As evident by the fact that the optimum amounts of sterile nutrient such as glucose, and nitrate and mineral salts are explicitly disclosed by the referenced inventions of Larsen & Joergensen, Atlas & Parks and Patz et al; see discussions above). The selection of specific ratios to be used of the nutrient components (in relation to the biomass used) in the claimed growth substrate composition would have been a routine matter of optimization on the part of the artisan of ordinary skill, said artisan recognizing that it is a routine procedure to optimized the ratios of ingredients for the culture of any given individual microorganism (relative to other components or nutrients used in the composition) in order to obtain an optimum growth rate and yield of specific cultured microbial product, or a desired microbial biomass. Furthermore, given the fact that sterile nutrients such as

Art Unit: 1657

nitrate and mineral salts have been used by Bothe et al (in view of Larsen & Joergensen) in the cultivation of Methanotrophic bacteria (such as *Methylococcus capsulatus* (Bath) strain) using the composition as claimed, it would have been a matter of routine optimization of the medium composition as well as of specific ratios of the sterile nutrient in relation to the biomass used to arrive at an optimum growth substrate composition. Therefore, a holding of obviousness over the cited claims is proper.

Thus, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the microbial art at the time this invention was made.

As per MPEP 2144.05 [R3], II. OPTIMIZATION OF RANGES - A. Optimization Within Prior Art Conditions or Through Routine Experimentation: *Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation."* In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

As per MPEP 2144.06, *"It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art."* In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

As per MPEP 2111.01, *during examination, the claims must be interpreted as broadly as their terms reasonably allow. In re American Academy of Science Tech Center, F.3d, 2004 WL 1067528 (Fed. Cir. May 13, 2004)(The USPTO uses a different standard for construing claims than that used by district courts; during examination the USPTO must give claims their broadest reasonable interpretation.). This means that the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).*

Response to Arguments Over Obviousness rejection

Applicant's arguments with respect to claims 11-14, 25-27, 30-33, 35 and 37 (as they pertain to the prior art rejection of record) have been considered but are not found to be persuasive for the following reasons of record.

Applicants argue the following (see response, page 11-12, in particular):

Art Unit: 1657

“Initially, Applicants note that the nutritional needs of different bacterial species differ remarkably, and for this reason, it **would not have been obvious** to one of skill in the art whether a biomass generated from methanotrophic and heterotrophic bacteria would be **suitable as a "broad-spectrum" growth substrate** for microorganisms.”

In response, it is noted that claims are directed to a product-by-process, which is a “sterile microorganism growth substrate”, comprising a biomass generated from the autolysis of bacterial cells comprising methanotrophic and heterotrophic bacteria (as recited in claims 11 and 37). The cited prior art references disclose such a biomass generated from (see teachings above of Bothe et al in view of Norferm, DA and Larsen & Joergensen) specific methanotrophic and heterotrophic bacteria, which can be used and modified by an artisan of ordinary skill in the microbial art (see 103a rejection above) to prepare a growth substrate (by adding and/or substituting various nutrients, such as carbon source, nitrogen source, etc.) that is suitable for growth of various microorganisms. Applicant’s argument that the growth substrate disclosed in the cited prior art is not suitable as a "broad-spectrum" growth substrate for microorganisms, is not found to be persuasive because claims, as presented do not specifically require such limitations. Moreover, since, the same biomass has been disclosed in the art for use as a bacterial growth substrate (see teachings of Patz et al for the preparation of a hydrolysate generated from the biomass of methanotrophic bacteria), albeit for the growth of same bacterium, it does not necessarily make it unsuitable for the growth of other microorganisms (for example, different bacterial strains, fungi, algae, etc.). Applicants have not provided such evidence on record to substantiate the arguments as currently being made.

Applicants further argue the following (see page 13-14):

“As discussed in Example 2 in the specification as filed, growth media were produced using the "BP Autolysate" and "BP Extract" biomasses. As shown in Table 1 on page 8 of the specification as filed, the growth media containing the "BP Autolysate" and "BP Extract" biomasses allowed superior growth of exemplary gram-positive, gram-negative, aerobic and anaerobic bacteria when compared to the control growth media, for the majority of the bacteria tested. Applicants note that the control growth substrates

Art Unit: 1657

used in the experiments depicted in Table 1 were not "broad-spectrum" growth substrates, but were in fact growth substrates recognized to be specifically suitable for growing the particular species of bacteria tested. Thus, even assuming *arguendo* that one of ordinary skill in the art would consider using a biomass generated from methanotrophic and heterotrophic bacteria as a sterile microorganism growth substrate, nothing in the art would lead one of ordinary skill in the art to expect that the claimed growth substrate would allow superior growth of even a single species of microorganism vis-a-vis the non-broad spectrum control growth substrate, which as discussed above, is recognized in the art as being specifically suitable for growing that particular microorganism. Accordingly, it would have been entirely unexpected that the claimed growth substrate would allow superior growth across a broad-spectrum of different bacteria, i.e., gram-positive, gram-negative, aerobic and anaerobic bacteria, when compared to the respective non broad-spectrum control growth substrate, wherein each control substrate is recognized in the art as being specifically suitable for growing the particular microorganisms tested. That Applicants' claimed growth substrates are superior to even the control substrates for the majority of the bacteria tested could not have been expected, and is further probative of the non-obviousness of the claimed invention."

In response, it is noted that the invention as claimed is directed to **a product** (i.e. a microorganism growth substrate composition), which has been disclosed in the cited prior art as a protein-rich biomass (i.e. single cell protein generated by ultrafiltration and evaporation, and containing 70% high quality proteins) that can be used for various purposes, including food and feed (i.e. both as a nutritional source and as a functional ingredient; see disclosure of Norferm, DA), and the hydrolysed biomass derived from a methanotrophic bacteria (see disclosure of Patz et al) have been used in the prior art as a growth substrate for culturing bacteria, in addition to the prior art (related to microbial culture media) that have disclosed the use of, for example, yeast extract, etc. as being suitable for growth of various bacteria and other microorganisms (see disclosure of Atlas & Parks). In short, given the disclosure in the cited prior art, it would have been obvious to an artisan of ordinary skill in the microbiological art at the time this invention was made to use the biomass generated from methanotrophic bacteria (i.e. single cell protein-rich biomass, albeit after cell lysis) as a growth substrate for microorganisms by using the modifications as discussed in the above rejection. Moreover, applicants arguments regarding "superior growth" and "specifically" suitable for growing a particular species of bacteria, is not found to be persuasive because instant claims are not directed to a method or process of culturing

Art Unit: 1657

or growing certain microorganism using such composition as claimed. The claims are directed to a product-by-process which has been reasonably disclosed by the cited prior art to be suitable for the same purpose, especially as being protein-rich nutrient and energy source (see disclosure of Norferm, DA, data sheet for "BioProtein", in particular, and the disclosure of Patz et al for the preparation of a bacterial hydrolysate taken to be the same as obtained by autolysis), which in the absence of any evidence to the contrary, would be expected by an artisan of ordinary skill in the art to be suitable for growth of any microorganism, including bacteria, molds, algae, etc. Since, all the components of the claimed composition are disclosed and/or suggested by the combination of cited prior art references, the obviousness rejection of record is deemed proper, and is therefore, maintained.

Obviousness-type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 11-14, 25-27, 30-33, 35, and 37 are/remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8 and 13-25 and 27 of copending Application No. **10/504,463** (same inventive entity, same assignee). Although the conflicting claims are not identical, they are not patentably distinct from each other because pending claims in said co-pending application are also directed to a product-by-process (i.e. a composition), which is derived from a biomass autolysate generated from the cultured

Art Unit: 1657

biomass of a methanotrophic bacterium. Since, the two sets of pending claims are co-extensive in scope, an obviousness-type double patenting rejection is clearly required.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to ODP Arguments

Since, applicants have deferred an appropriate response at the present time (see response, page 15, 2nd paragraph, in particular), the provisional ODP rejection of record, as set forth in the previous office action and as discussed above over the co-pending application 10/504,463, is still maintained.

However, in view of the amendments to the claims in the co-pending application 10/504,464, the ODP rejection of record as set forth in the previous office action, has been withdrawn.

Conclusion

NO claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SATYENDRA K. SINGH whose telephone number is (571)272-8790. The examiner can normally be reached on 9-5MF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Satyendra K. Singh/
Examiner, Art Unit 1657

/Irene Marx/
Primary Examiner
Art Unit 1651

Application/Control Number: 10/511,685

Page 14

Art Unit: 1657